

A TEST STRIP IGM DOT-ELISA ASSAY USING LEPTOSPIRAL ANTIGEN OF ENDEMIC STRAINS FOR SERODIAGNOSIS OF ACUTE LEPTOSPIROSIS

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ABSTRACT

A test strip IgM dot-ELISA assay for the detection of leptospire-specific IgM antibodies in human sera was developed. Antigen dotted on a nitrocellulose paper strip was the pool-solicited antigen prepared from three predominant reactive *Leptospira* serovars currently in endemic area, i.e., bratislava, sejroe and pyrogenes. The ability of the test to diagnose acute leptospiral infection was assessed by testing 343 single serum samples from 96 laboratory-confirmed leptospirosis case patients with positive result in the standard microscopic agglutination test (MAT), 55 serum samples from patients with various diseases other than leptospirosis, and 192 serum samples from healthy individuals. Using the results of the MAT as a gold standard, the sensitivity and specificity of the test strip IgM dot-ELISA assay were 98.96 and 93.93 percent, respectively. The assay offered relatively high negative predictive values (99.57%) thus making the assay ideally suited for rapid screening. The stability of the test strip was assessed with a panel of five positive and five negative control sera after storage at 4°C and -20°C at different times. The results showed a good performance of the test strip at both storage temperatures for up to one year. In conclusion, the test strip IgM dot-ELISA assay was sufficiently sensitive for use as a screening test for serodiagnosis of acute leptospirosis. The assay was simple, inexpensive, and easy to perform for both a single test format and a large number of specimens. However, further studies are still needed to improve the stability of the test strip and assay reagents at ambient temperature, and to make the assay more rapidly and more users friendly.

Key word: Leptospirosis, Serodiagnosis, Test strip IgM dot-ELISA assay, Endemic leptospiral antigens
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